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10/550,100	09/21/2005	Ryosuke Yamada	28951-5426	8385

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EXAMINER	
HENSON, MISCHITA L	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,100	YAMADA ET AL.	
	Examiner	Art Unit	
	Mi'schita' Henson	2857	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 September 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *21 September 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is responsive to the amendment filed on September 21, 2005. Claims 3, 7-8,11 and 14 have been amended. Claims 1-15 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 5-11 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 5 (lines 13 and 17), 7 (lines 2-3), 9 (lines 12 and 18) and 15 (line 6), the limitations in parenthesis may lead to confusion over the intended scope of the claim; it is not clear whether the limitations in the parenthesis are in fact a limitation; therefore, the claim is indefinite because the intended scope of the claim is unclear.

Claims 6, 8 and 10-11 inherit the limitations of the claims from which they depend.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

1. Claims 5-15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In order to be considered patent eligible under

35 USC 101, a claimed process must either result in a physical transformation or contain a sufficient tie to a particular machine or apparatus.

Claims 5, 9, 12 and 15 do not result in any physical transformation nor recite a sufficient tie to a particular machine or apparatus in that the steps are not being performed by a machine or apparatus.

Claims 6-8, 10-11 and 13-14 do not remedy the deficiency of the claims from which they depend, with respect to 35 USC 101.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-5, 8-9 and 11-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Hurt et al. in US Publication 2003/0224457.

Regarding claim 1, Hurt et al. teaches:

An analysis apparatus (see clinical diagnostic assays, Abstract; see analyzer, [0120] and [0167]), in which a specimen containing cells is applied onto a disc, light is emitted to the disc, and the number of cells is determined based on reflected or transmitted light (see optical bio-disc, [0014]; see also reflective disc and transmission disc, [0016]), the analysis apparatus comprising:

a one-dimensional cell recognition section for one-dimensionally recognizing the cell based on a change of the reflected or transmitted light (see identification of cell types, [0003]; see also incident beam of electromagnetic radiation, [0020] and [0024]),

a specimen memory for storing first data in a bit corresponding to each track of the disc based on a recognition result of the one-dimensional cell recognition section, the first data indicating presence or absence of the cell (see memory, [0205] and [0208] and see Fig. 20),

a two-dimensional cell recognition section for two-dimensionally recognizing the cell by scanning the specimen memory with a window having a given size to confirm the first data (see scanning the chamber with an incident beam of electromagnetic radiation by rotating the disc about an axis substantially perpendicular to the first side by moving the incident beam in a direction radial to the axis, [0020]; see capture field, [0014], [0043] and [0105]),

a data addition section for adding second data to the specimen memory for each window, the second data indicating presence or absence of the cell in the two-dimensional cell recognition (see determining the presence of antibodies in the sample, [0020] and Fig. 20),

a cell size identification section for identifying a cell size by using the second data (see expected or detected size of the spots, [0204]), and

a window movement control section for controlling movement of the window, wherein the second data indicating the presence or absence of the cell for each window is added to the specimen memory, so that a cell size and the number of cells are

obtained with one data acquisition (see analysis of the measurement profile is controlled by the software, [0017]; see controller, [0120] and [0167]; see control capture field, [0148]; see conduction cell counts and differential cell counts, [0102]; see cell counting technique, [0195]).

Regarding claim 2, Hurt et al. teaches:

An analysis apparatus (see clinical diagnostic assays, Abstract; see analyzer, [0120] and [0167]), in which a specimen containing cells is applied onto a disc, light is emitted to the disc, and the number of cells is determined based on reflected or transmitted light (see optical bio-disc, [0014]; see also reflective disc and transmission disc, [0016]), the analysis apparatus comprising:

a one-dimensional cell recognition section for one-dimensionally recognizing the cell based on a change of the reflected or transmitted light (see identification of cell types, [0003]; see also incident beam of electromagnetic radiation, [0020] and [0024]),

a specimen memory for storing first data in a bit corresponding to each track of the disc based on a recognition result of the one-dimensional cell recognition section, the first data indicating presence or absence of the cell (see memory, [0205] and [0208]),

a two-dimensional cell recognition section for two-dimensionally recognizing the cell by scanning the specimen memory with a window having a given size to confirm the first data(see scanning the chamber with an incident beam of electromagnetic radiation by rotating the disc about an axis substantially perpendicular to the first side by moving

the incident beam in a direction radial to the axis, [0020]; see capture field, [0014], [0043] and [0105]),

a window switching section for arbitrarily switching a size of the window during scanning of the specimen memory (see different target zones can be constructed with different capture agents on the same or different optical bi-discs, [0139]),

a cell size identification section for identifying a cell size recognized from a scanning result obtained with one or more window sizes in the two-dimensional cell recognition section (see expected or detected size of the spots, [0204]), and

a data deletion section for deleting the first data after identification in the cell size identification (see CD-R or DVD-R, [0016], [0023], [0027] and [0036]),

wherein when a cell is confirmed during scanning of the specimen memory, a cell size is identified by changing the window size and performing rescanning, so that a cell size and the number of cells are obtained with one data acquisition (see control capture field, [0148]; see conduction cell counts and differential cell counts, [0102]; see cell counting technique, [0195]).

Regarding claim 3, Hurt et al. teaches the limitations of claim 1 as indicated above. Further, Hurt et al. teaches:

The analysis apparatus according to claim 1, wherein a sampling period can be changed with the size of the cell in the specimen (see a sampling rate and optionally a bio-disc rotation speed is adjusted to correspond to the expected or detected size of the spots, [0204]).

Regarding claim 4, Hurt et al. teaches the limitations of claim 1 as indicated above. Further, Hurt et al. teaches:

The analysis apparatus according to claim 1, further comprising a cell spacing memory for storing a spacing between the cells during scanning of the specimen memory with the window (see memory, [0205] and [0208]), and a memory skip control section for scanning only an area having the cell based on information from the cell spacing memory when the window size is switched to rescan the specimen memory (see an alignment mark is pre-disposed on the bio-disc specifically to allow the software to determine a starting point on the track from which to determine an offset point for the capture zone of interest. The alignment symbol may include a solid black India ink dot positioned near the start of a capture zone, [0209]) .

Regarding claim 5 (as is best understood), Hurt et al. teaches:

A cell counting method in an analysis apparatus (see clinical diagnostic assays, Abstract; see analyzer, [0120] and [0167]), the method comprising:

reading a data array (see bio-matrix, [0028]-[0031]) in an area of a scanning window (see target zones or fields, [0139]) from memory for storing the data array (see memory, [0205] and [0208]) having binary data of "0" or "1" surface-aligned along a lateral direction X and a longitudinal direction Y (see area encoded with information that sends data to the processor, [0103]), the binary data being obtained based on presence or absence of cells applied with two or more sizes on an analysis disc (see presence or absence of antibody to A and/or B antigen, [0020], [0022] and Fig. 20), the scanning window movable in the lateral direction X and the longitudinal direction Y and having a

size expressed by rows x X, the rows being aligned along the X direction of the data array (see scanning the chamber with an incident beam of electromagnetic radiation by rotating the disc about an axis substantially perpendicular to the first side by moving the incident beam in a direction radial to the axis, [0020]; see trigger markings and target zones, [0113] and Fig. 8),

performing an operation based on the data to decide the presence or absence of the cells (see analyzing the output signal to determine the presence of agglutinated cells, [0020] and [0024]),

identifying cell sizes (see expected or detected size of the spots, [0204]), and

counting the number of the cells for each of the cell sizes (see conduct the cell counts, [0102]),

wherein the scanning window is constituted of a first window for deciding whether "0" is present over an area of the first window with a size of 1 x X1 (X1 is an integer constant), a second window for deciding whether "1" is included in an area of the second window positioned with a size of 1 x 1 at a center of the X direction of the first window in a subsequent row of the first window, and a third window for deciding whether at least one "1" is included in each row of an area of the third window positioned with a size of Y × X1 (Y is an integer variable) in a subsequent row of the second window, and the cell sizes are identified using the scanning window (see display monitor, [0102]; see a clear window on all three layers, [0103] and [0108]; see trigger markings and targets zones, [0113] and Fig. 8).

Regarding claim 8 (as is best understood), Hurt et al. teaches the limitations of claim 5 as indicated above. Further, Hurt et al. teaches:

The cell counting method in the analysis apparatus according to claim 5, wherein presence or absence of the cell is decided according to a change in light quantity when laser light is emitted to a track on the analysis disc where the cell is applied and when the laser light is received by a photodetector (see incident beam of electromagnetic radiation…detecting a return beam of electromagnetic radiation, [0020] and [0024]).

Regarding claim 9 (as is best understood), Hurt et al. teaches:

A cell counting method in an analysis apparatus (see clinical diagnostic assays, Abstract; see analyzer, [0120] and [0167]), the method comprising:

reading a data array (see bio-matrix, [0028]-[0031]) in an area of a scanning window (see target zones or fields, [0139]) from memory (see memory, [0205] and [0208]) for storing the data array having binary data of"0" or "1" surface-aligned along a lateral direction X and a longitudinal direction Y (see area encoded with information that sends data to the processor, [0103]), the binary data being obtained based on presence or absence of cells applied with two or more sizes on an analysis disc (see presence or absence of antibody to A and/or B antigen, [0020], [0022] and Fig. 20), the scanning window movable in the lateral direction X and the longitudinal direction Y and having a size expressed by rows x X, the rows being aligned along the X direction of the data array (see scanning the chamber with an incident beam of electromagnetic radiation by rotating the disc about an axis substantially perpendicular to the first side by moving the

incident beam in a direction radial to the axis, [0020]; see trigger markings and target zones, [0113] and Fig. 8),

deciding the presence or absence of the cells based on the data (see analyzing the output signal to determine the presence of agglutinated cells, [0020] and [0024]),

identifying the sizes of the cells (see expected or detected size of the spots, [0204]), and

counting the number of the cells for each cell size (see conduct the cell counts, [0102]),

wherein the scanning window is constituted of a first window for deciding whether "0" is present over an area of the first window with a size of I x XI (XI is an integer constant), a second window for deciding whether "I" is included in an area of the second window positioned with a size of I x I at a center of the X direction of the first window in a subsequent row of the first window, a third window for deciding whether at least one "I" is included in each row of an area of the third window positioned with a size of YI x X1 (YI is an integer variable) in a subsequent row of the second window, and a fourth window for deciding whether "0" is present over an area of the fourth window positioned with a size of I x XI (XI is an integer variable) in a subsequent row of the third window, and the cell sizes are identified using the scanning window (see display monitor, [0102]; see a clear window on all three layers, [0103] and [0108]; see trigger markings and targets zones, [0113] and Fig. 8).

Regarding claim 11 (as is best understood), Hurt et al. teaches the limitations of claim 9 as indicated above. Further, Hurt et al. teaches:

The cell counting method in the analysis apparatus according to claim 9, wherein presence or absence of the cell is decided according to a change in light quantity when laser light is emitted to a track on the analysis disc where the cell is applied and when the laser light is received by a photodetector (see incident beam of electromagnetic radiation…detecting a return beam of electromagnetic radiation, [0020] and [0024]).

Regarding claim 12, Hurt et al. teaches:

An analysis apparatus (see clinical diagnostic assays, Abstract; see analyzer, [0120] and [0167]), in which detection light is emitted to an analysis disc where cells are applied (see optical bio-disc, [0014]; see also reflective disc and transmission disc, [0016]), and the cells are counted based on data received by a photodetector (see conduct the cell counts, [0102]), the analysis apparatus comprising:

a memory for storing binary cell information for each bit of a data bus (see memory, [0205] and [0208]), the cell information being obtained for each track on the analysis disc (see a spiral track that starts at an innermost readable portion of the disc, [0115]; see tracks, [0125]),

a window movable in an area of the memory (see target zones or fields, [0139]),

a window movement control section for controlling a movement of the window (see controller, [0120] and [0167]; see control capture field, [0148]),

a cell size determination section for recognizing the cell from an array of "1" in the window and determining a cell size (see expected or detected size of the spots, [0204]),

a cell counting section for incrementing a counter after recognition of the cell (see conduct the cell counts, [0102]), and

a memory rewriting section for rewriting "1" to "0" after the recognition of the cell (see CD-R or DVD-R, [0016], [0023], [0027] and [0036]).

Conclusion

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Fors et al. in US Publication 2003/0082544 teaches “The present invention provides systems and methods for acquiring and analyzing biological information. In particular, the present invention provides systems and methods for developing detection assays and for use of detection assays in basic research discovery to facilitate selection and development of clinical detection assays. As a detection assay is moved from research to clinical use, the cost to produce it does not increase significantly, while the revenue and profit margin it generates increase exponentially” ([0002]) and “The ability to detect the presence or absence of specific target sequences in a sample underlies much of the fields of molecular diagnostics and molecular medicine” ([0155]).

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mi'schita' Henson whose telephone number is (571) 270-3944. The examiner can normally be reached on Monday - Thursday 7:30 a.m. - 4:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Eliseo Ramos-Feliciano can be reached on (571) 272-7925. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

03/21/09

/Mi'schita' Henson/
Examiner, Art Unit 2857

/Hal D Wachsman/
Primary Examiner, Art Unit 2857